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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/552,705 04/19/00 CHEN

S 2124-311

EXAMINER

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HM22/0813

FRONDA, C

ART UNIT	PAPER NUMBER
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1652

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DATE MAILED:

08/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/552,705</b>	Applicant(s) <b>Chen et al.</b>	
	Examiner <b>Christian L. Fronda</b>	Art Unit <b>1652</b>	

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)  Responsive to communication(s) filed on \_\_\_\_\_.

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4)  Claim(s) 43-52 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 43-52 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      20)  Other: \_\_\_\_\_

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## DETAILED ACTION

1. In the AMENDMENT dated May 29, 2001 (paper no. 8), Applicants have amended claim 47.
2. Claims 44-52 are under consideration in this Office Action.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 43-52 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed on May 29, 2001 (paper no. 8), have been fully considered but they are not persuasive. Applicants argue that the specification enables one of ordinary skill in the art to perform each step of claims 43 and 52 and that the claims are drawn to a method of screening for a protein which interacts with a chemical and that there is a disclosure of a structure to function/activity.

As stated in the Office Action dated February 27, 2001 (paper no. 7), the specification, only provides the following representative species of chemicals encompassed by these claims: estradiol, dexoxycorticosterone, progesterone, and retionic acid. There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The chemicals encompassed by the claim are expected to differ with respect to chemical formula and chemical property. The specification also fails to describe additional representative species of these chemicals by any identifying structural characteristics or properties other than the chemical promoting the binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain for which no predictability of structure is apparent. Given this lack of additional representative species of chemicals as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact

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terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

The specification discloses that PNRC (proline-rich nuclear receptor co-regulatory protein) has an amino acid sequence of 327 amino acid residues (SEQ ID NO: 8). The amino acid sequence of SEQ ID NO: 5 which consists of seven amino acid residues was identified as a binding motif in the disclosed PNRC having the amino acid sequence of SEQ ID NO: 8. The amino acid sequence of SEQ ID NO: 9 is disclosed as consisting of 23 amino acid residues which comprises SEQ ID NO: 5.

The claims encompass any protein of any amino acid sequence which comprises SEQ ID NO: 5 or SEQ ID NO: 9. However, the specification does not provide a written description of any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 because the specific amino acid sequence that is N-terminal and C-terminal to SEQ ID NO: 5 or SEQ ID NO: 9 has not been described. The disclosed PNRC having SEQ ID NO: 8 is the single representative species of a protein comprising SEQ ID NO: 5 or SEQ ID NO: 9. The specification also fails to describe additional representative species of the claimed proteins by any identifying structural characteristics or properties other than the protein having SEQ ID NO: 5 or SEQ ID NO: 9, for which no predictability of structure is apparent. Given this lack of additional representative species of proteins comprising SEQ ID NO: 5 or SEQ ID NO: 9 as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 44-51 which depend from claim 43 are also rejected because they do not correct the defect of claim 43.

5. Claims 43-52 are again rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein having an amino acid sequence consisting of SEQ ID NO: 8 and the hormone or ligand selected from the group consisting of estradiol, dexamycorticosterone, progesterone, and retionic acid; does not reasonably provide enablement for any chemical or any protein comprising an amino acid sequence set forth in SEQ ID NO:5 or SEQ ID NO: 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments filed on May 29, 2001 (paper no. 8), have been fully considered but they are not persuasive. Applicants argue that the specification contains illustrative examples and terminology to teach one of ordinary skill in the art how to make and use the invention as broadly claimed. Applicants argue with regard to a search for the biological function, biological activity, or utility of the claimed protein comprising SEQ ID NO:5 or SEQ ID NO: 9 that such search is not necessary since the claims are drawn to methods.

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The nature and breadth of the claims encompasses any chemical or any protein comprising an amino acid sequence set forth in SEQ ID NO:5 or SEQ ID NO: 9. The specification provides guidance and examples for using the ligand or hormones selected from the group consisting of estradiol, dexoycorticosterone, progesterone, and retionic acid and the PNRC protein having an amino acid sequence consisting of SEQ ID NO:8. The specification does not provide guidance in using any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 other than the PNRC protein having an amino acid sequence of SEQ ID NO: 8 in the claimed screening method. Because the claims encompass any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9, knowledge regarding the biological function, biological activity, or utility of a protein comprising SEQ ID NO:5 or SEQ ID NO: 9 is required in order to determine if the claimed protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 can be used in the claimed screening method. Experimentation must be conducted to determine whether any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 can be used in the claimed screening method.

The specification discloses that PNRC having an amino acid sequence of SEQ ID NO: 8 interacts with nuclear receptors but does not disclose that any protein comprising SEQ ID NO:5 or SEQ ID NO: 9 interacts with nuclear receptors. Thus, an undue amount of experimentation must be conducted to determine whether any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 interacts with nuclear receptors and thus can be used in the claimed screening method. Such experimentation entails screening a vast number of organisms for a protein comprising the claimed amino acid sequences of SEQ ID NO:5 or SEQ ID NO:9, isolating the gene encoding the protein from libraries prepared from the selected organism, expressing the protein, and determining whether the protein interacts with nuclear receptors and can be used in the claimed screening method. Determining whether any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 can be used in the claimed screening method is well outside the realm of routine experimentation and predictability in the art of success is extremely low. In addition, experimentation involving screening for chemicals which promote the binding of any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 to nuclear receptors is well outside the realm of routine experimentation.

Because the specification does not teach how to use the claimed screening method with any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 and the amount of experimentation to determine whether any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 interacts with nuclear receptors is undue, the specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims. Claims 44-51 which depend from claim 43 are also rejected because they do not correct the defect of claim 43.

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***Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 43-52 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants' arguments filed on May 29, 2001 (paper no. 8), have been fully considered but they are not persuasive. Applicants argue that the present invention is to screen chemicals for activity and that it is not necessary to specify a chemical. The claims are directed toward a screening method for identifying proteins which interact with any chemical. Claim 43 and 52 are indefinite because the chemical that interacts with the protein is not known and has not been defined. Claims 42-51 which depend from claim 43 are also rejected because they do not correct the defect of claim 43.

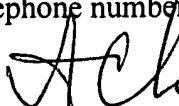
***Conclusion***

8. No claim is allowed.

9 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

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